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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' BRIEF REGARDING RECONSIDERATION OF ISSUES DECIDED IN THE BOOKER MATTER

(Assigned to the Honorable David G. Campbell)

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Bard submits this brief concerning issues decided with the *Booker* trial that it believes should be reconsidered for the *Jones* trial. Bard respectfully asks this Court to reconsider its rulings (*see* Dkt. Nos. 10258, 10323, & 10565) regarding Bard's Motion in Limine No. 1 (Dkt. No. 9862) concerning Recovery Filter complications, Motion in Limine No. 2 (Dkt. No. 9863) concerning Recovery Filter development, and Motion in Limine No. 3 (Dkt. No. 9864) concerning the FDA Warning Letter.

ARGUMENT AND CITATION TO AUTHORITIES

A. Evidence Regarding Recovery Filter Complications and Development Should Be Excluded as Irrelevant Under Rule 402.

This Court previously found that evidence of Recovery Filter complications was relevant in the *Booker* matter because that case involved a G2 Filter, and because "Bard's knowledge of problems with the Recovery filter is relevant to . . . whether Bard properly designed the G2 to correct those problems, [and] whether Bard failed to warn physicians and patients about problems shared by the Recovery and G2." (*See* Dkt. No. 10258 at 3.) This Court further observed that "it would be difficult to try" the *Booker* matter because "evidence regarding FDA clearance will necessarily include the fact that the Recovery filter was the predicate device for the G2 and was substantially equivalent to the G2." (*Id.*) Similarly, regarding evidence of the development of the Recovery, this Court based its decision that such evidence was admissible because "Bard based its request for FDA clearance of the G2 on the claim that it was substantially equivalent to, and as safe and effective as, the Recovery." (*Id.* at 5.)

These considerations are not applicable in this ***Eclipse Filter*** case. Bard obtained FDA clearance for the Eclipse on January 14, 2010, approximately 4 1/2 years after Bard stopped selling the Recovery in 2005, approximately 7 1/2 years after FDA first cleared the Recovery in 2003, and more than 8 years after the development of the Recovery was completed.

The predicate device for the Eclipse is the G2 Express, which was cleared on October 31, 2008. Unlike the G2, the Eclipse is not an attempt to "correct" problems

with the Recovery. And, unlike with the G2, evidence concerning FDA's clearance of the Eclipse does not require discussion of substantial equivalence to the Recovery. Instead, Bard will present evidence that the Eclipse is an improvement upon -- and substantially equivalent to -- Bard's G2 and G2 Express Filters.[1] Thus, evidence concerning the Recovery's development or complications is too attenuated and removed in time to be relevant in this Eclipse matter.

B. Evidence Regarding Recovery Filter Cephalad Migration Deaths Should Be Excluded Under Rule 403.

This Court concluded that evidence of Recovery Filter cephalad migration deaths is relevant in the *Booker* case because it would be "necessary for the jury to understand the issues that prompted creation and design of the G2, information that is relevant to the design defect claim." (Dkt. No. 10323 at 4.) The Court also found "such evidence relevant in responding to Defendants' assertion that the FDA's 510(k) clearance of the G2 amounted to a determination that the G2 was as safe and efficient as the Recovery." (*Id.*) For the reasons explained above, these considerations regarding the direct connection between the Recovery and G2 Filters are simply not applicable in this case concerning the Eclipse, which is three generations removed from the Recovery.

More importantly, any tangential probative value that Recovery cephalad migration evidence may have will be substantially outweighed by the unfair prejudice, confusion of issues, and waste of time that will result from the admission of such evidence. *See* Fed. R. Evid. 403. In the *Booker* matter, the plaintiff called two live witnesses -- Alex Tessmer and Dr. Murray Asch -- who testified exclusively regarding Recovery Filter development and testing. And even though the case concerned a G2, the plaintiff in *Booker* admitted approximately 33 exhibits that concerned exclusively or

[1] The G2 and G2 Express Filters are identical, except that the G2 Express includes an electropolished, snarable hook at the top of the device. The Eclipse has the same dimensions as the G2 Express, except that wires of the filter are electropolished prior to forming the filter. Electropolishing is a manufacturing process that improves the surface finish of the wires that form the device.

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almost exclusively the Recovery Filter. These included many documents concerning Recovery cephalad migration-related death. But this unique type of complication -- the cephalad migration of an entire filter to a patient's heart, allegedly causing or contributing to the patient's death -- is simply not at issue in Ms. Jones's case. Her case involves an Eclipse filter that fractured, with a single piece of the filter embolizing to her right lung. There is absolutely no allegation that Ms. Jones's entire filter migrated in the cephalad direction, much less migrated to her heart causing death. Indeed, to Bard's counsel's knowledge, there is not a single reported event where an Eclipse Filter (or a G2 or G2 Express) migrated to a patient's heart allegedly causing death.

If Plaintiff repeats what was done in the *Booker* matter and admits substantial evidence concerning Recovery cephalad migration-related deaths, the jury will be invited to assume that such complications associated with the Recovery are also applicable to Eclipse, resulting in potential juror confusion. Bard will need to expend substantial time explaining the differences between the Recovery and Eclipse Filters, and will need to demonstrate how the changes and evolution of Bard's IVC filters over a 6 or 7 year period virtually eliminated cephalad migration to the heart as a serious complication associated with the Eclipse. Admitting evidence of Recovery cephalad migration-related deaths will result in Bard being unfairly prejudiced.

C. Evidence Regarding the FDA Warning Letter Should Be Excluded Pursuant to Rules 401, 402, and 403.

In *Booker*, this Court admitted evidence concerning Item No. 3 of the FDA Warning Letter, finding that it was relevant because it concerned "handing and reporting of adverse events with respect to the G2 Filter in at least four different instances." (*Booker* Trial Tr. at 1888:25 to 1889:1; *see also* M.E. 3.27.2018 [Dkt. No. 10565].) But unlike the G2 Filter, the Eclipse Filter is addressed in Warning Letter Item No. 3 on only 1 occasion. (*See* FDA Warning Letter, previously filed at Dkt. No. 10523-1, Item 3.b. ("Complaint 628924, Eclipse Filter, detached filter limb resulting in pericardial effusion and cardiac catheterization.").) Here, although Plaintiff did experience an Eclipse Filter

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fracture, she did not have a resulting pericardial effusion and cardiac catheterization. And there is no allegation that the handling of Plaintiff's complaint or Medical Device Report to FDA was deficient or violative of FDA regulations. Indeed, Bard received notice of Plaintiff's complaint and submitted its MDR Report to FDA in March 2016, approximately 8 months after the FDA Warning Letter was issued. Thus, Warning Letter Item No. 3.b is not relevant in this case.

The remaining portions of Item No. 3 are not relevant to Plaintiff's case. As mentioned during the *Booker* trial, Item No. 3.a concerns root cause analysis of complaints involving component parts supplied by third-party manufacturers, which is an issue that by definition concerns only Bard's Denali Filter. Item No. 3.c concerns various unidentified Bard IVC Filters[2] with allegations that Bard's complaint file documentation was deficient. Here, there is no allegation that Bard's handling of Plaintiff's internal complaint was deficient in any manner.

Finally, here (as in *Booker*), the implanting physician did not testify he specifically relies on MAUDE to make treatment decisions and did not testify that he would have made a different decision in regard to using the Eclipse Filter based on any information in the MAUDE database. Thus, like this Court found in *Booker*, any failure by Bard to timely or accurately report complications to the FDA could not have had any causative impact on Plaintiff's claims or injuries. (*Cf. Booker* Trial Tr. at 1888:5-11 ("The argument that was made by the defendants in the brief was largely a causation argument, that none of the complaints could have caused Ms. Booker's injuries because they were either after the implant or the doctors who removed the filter had no knowledge of those complaints. I agree with that. I don't think it goes to causation.").

Accordingly, the FDA Warning Letter is simply not relevant in this Eclipse Filter matter. *See* Fed. R. Evid. 401 & 402. Even if the Letter had marginal relevance, the

[2] Bard was able to determine that 1 of the 10 patients referenced in Item No. 3.c received a G2 Filter, but was unable to determine the models of filters for the other patients.

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prejudicial impact of the Letter on Bard would substantially outweigh its probative value. The jury would be invited by Plaintiff to believe that the Warning Letter somehow implicates the design or warnings associated with the Eclipse Filter, even though nothing in the Letter suggests any such deficiencies. And Bard would be forced to put the Warning Letter into proper context, not only through the testimony of one or two fact witnesses, but also through expert regulatory witness testimony. The Warning Letter would become a substantial "side-show" in this matter, confusing and distracting the jury from the true issues in this matter. Therefore, it should be excluded under Fed. R. Evid. 403.

CONCLUSION

For the stated above, Bard respectfully asks this Court to reconsider its rulings regarding Bard's Motions in Limine Nos. 1, 2, and 3. Specifically, Bard asks that this Court find that evidence regarding the development of the Recovery Filter, Recovery Filter complications, and the FDA Warning Letter be excluded pursuant to Federal Rules of Evidence 401, 402, and 403.

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of April, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

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